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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,741	04/03/2001	Arthur W. Zikorus	VNUS-57380	4515

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EXAMINER	
ROY, BAISAKHI	
ART UNIT	**PAPER NUMBER**
3737	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/825,741	ZIKORUS ET AL.	
	Examiner	Art Unit	
	Baisakhi Roy	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,35-41,50-54 and 70-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,35-41,50-54 and 70-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-15 and 19-22 under Cohn '224 have been fully considered but they are not persuasive. The catheter in Cohn also applies energy to the anatomical structure via an energy application device to lead to a reduced diameter of the structure. While it is true that Cohn teaches cutting tissue, it is still applying energy to the structure and eventually leading to a smaller structure (col. 19 lines 8-28).

2. Applicant's arguments, with respect to the rejection(s) of claim(s) under Flaherty have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art.

3. Applicant's arguments, with respect to the rejection(s) of claim(s) under Dubrul have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

the claimed invention is directed to non-statutory subject matter. Claims 16, 17, and 50, claiming the anatomical structure which is considered to non-statutory subject matter.

For example, claim 16, line 3 should read "hook shaped tip adaptable to be engaged to the junction of the hollow anatomical junction."

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-15, 19-22, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohn et al. (5830224).

Cohn et al. disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction and applying energy to the anatomical structure and eventually leading to a smaller structure (col. 12 lines 4-7, col. 15 lines 14-32, col. 19 lines 30-52, col. 31 lines 50-53, claims 1, 2).

Cohn et al. teach emitting light from a fiber optic device by introducing the catheter over a fiber optic device and removing the fiber optic device after the step of measuring the length of the device into the patient until the attribute of light changes (col. 25 lines 16-33, col. 27 lines 25-61).

The reference teaches generating a magnetic field at the working end of the catheter and sensed by the catheter (col. 21 lines 64-67, col. 22 lines 1-63).

The reference teaches introducing the catheter over a guide wire and generating a magnetic field at and by the guide wire (col. 23 lines 25-30 lines 47-67, col. 24 lines 1-18).

The reference teaches generating a radio-frequency signal at the catheter and sensed by the catheter (col. 20 lines 13-23 lines 40-47, col. 22 lines 42-63, col. 28 lines 50-67, col. 29 lines 5-51, col. 31 lines 11-15).

The reference teaches generating an ultrasound signal at the working end of the catheter and sensed by the catheter and introducing the catheter over the guide wire with an ultrasound signal generated by the guide wire and sensed by the guide wire (col. 26 lines 4-65, col. 28 lines 1-11, col. 30 lines 28-36, col. 31 lines 9-28).

3. Claims 50, 52, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Leschinsky et al. (5728122). Leschinsky disclose a method of positioning a catheter within a hollow anatomical structure by introducing a guide wire having a hook-shaped tip, hooking the hook-shaped tip of the guide wire to the structure of interest, introducing a catheter having a working end into the hollow structure over the guide wire, and positioning the working end of the catheter proximate the structure of interest (abstract, col. 2 lines 8-23 lines 62-67 lines 1-5, col. 13 lines 43-46), and measuring the length of the guide wire (col. 9 lines 26-42).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn et al. in view of Leschinsky et al. (5728122). Cohn et al. do not explicitly teach the guide wire to have a hook shaped tip at the distal end. In the same field of endeavor, Leschinsky et al. disclose a guide wire with a hook shaped tip located at the working end of the catheter (col. 13 lines 43-47). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Leschinsky et al. to modify the teaching by Cohn et al. for the purpose of enabling a more efficient anchoring mechanism to attach to the structure of interest.

6. Claims 35, 37, 38, 40, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al. in view of Leschinsky et al. Flaherty et al. disclose a method of positioning a catheter within a hollow anatomical structure by determining a desired location within the hollow structure, marking the location, introducing a catheter having a working end with a transducer into the hollow structure, identifying the location of the transducer, and positioning the working end of the catheter at the desired location within the structure (col. 3 lines 23-67, col. 6 lines 6-16 lines 60-67, col. 11 lines 6-22, col. 19 lines 9-43, col. 23 lines 1-33, and claims 1, 5). The reference teaches using a device to be controlled by the operator positioned over the hollow structure, which identifies the location of the transducer (col. 3 lines 23-60), generating a magnetic field at the working end of the catheter (col. 4 lines 20-47), and an ultrasound signal at the working end of the catheter (col. 2 lines 41-55). Flaherty et al. however do not explicitly

teach the use of external markers. Leschinsky et al. however do teach the use of reference marks (col. 2 lines 25-29). It would have therefore been obvious to one of ordinary skill in the art to use the Leschinsky et al. teaching to modify the teaching by Flaherty et al. for the purpose of allowing more precise determination of the location of the vessel puncture (col. 2 lines 24-25).

7. Claim 36, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al. in view of Leschinsky et al. and further in view of Cohn et al. Flaherty et al. and Leschinsky et al. do not explicitly address the sapheno-femoral junction. Cohn et al. as discussed previously disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction and applying energy to the anatomical structure and eventually leading to a smaller structure (col. 12 lines 4-7, col. 15 lines 14-32, col. 19 lines 30-52, col. 31 lines 50-53, claims 1, 2). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Cohn et al. to modify the teaching by Flaherty et al. and Leschinsky et al. for the purpose of enabling a more detailed study of the sapheno-femoral junction and reduce the structure to a smaller size.

Flaherty et al. do not teach generating a radio-frequency field at the working end of the catheter. Cohn et al. teach a method of positioning a catheter within a hollow anatomical structure with the generation of a radio-frequency field at the working end of the catheter (col. 20 lines 13-23 lines 40-47, col. 22 lines 42-63, col. 28 lines 50-67, col. 29 lines 5-51, col. 31 lines 11-15). It would have therefore been obvious to one of ordinary skill in the art to use the radio-frequency teaching by Cohn et al. to modify the

teaching by Flaherty et al. for the purpose of obtaining feedback from the catheter from a radio-frequency signal.

8. Claims 51, 54, 73, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leschinsky et al. in view of Cohn et al. Leschinsky et al. do not explicitly teach using the apparatus near the viscinity of the sapheno femoral junction. Cohn et al. as discussed previously disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction and applying energy to the anatomical structure and eventually leading to a smaller structure (col. 12 lines 4-7, col. 15 lines 14-32, col. 19 lines 30-52, col. 31 lines 50-53, claims 1, 2). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Cohn et al. to modify the teaching by Leschinsky et al. for the purpose of providing a more detailed examination of a specific site of interest.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for other relevant references of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BR

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PRIMARY EXAMINER
ART UNIT 3737